



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NADA 141-108

Andrew T. Palmeter, D.V.M.
Associate Director, Regulatory Affairs
Fort Dodge Animal Health
Cyanamid Agricultural Center
P.O. Box 400
Princeton, NJ 08543-0400

AUG 17 1999

Dear Dr. Palmeter:

We refer to your promotional piece (a Videotape – VNR) for EtoGesic™ (etodolac) tablets, NADA 141-108 that was submitted as a DER dated August 1, 1999. The Videotape is determined to be labeling and as such it must include or be accompanied with full prescribing information, i.e., a package insert as required under 21 CFR 201.105(d). In addition, the promotional tape is deemed false, lacking in fair balance, or otherwise misleading in that it over emphasizes the safety and effectiveness of the product, but fails to mention any side effects in the narrative text in the same depth and detail.

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356V, that you will promote your product only in accordance with the labeling provided for in the approved application. We request that you immediately discontinue this violative VNR and in the future devise promotional material that are consistent with the drug promotion and advertising regulations.

Please inform us of your intentions as soon as possible or in any event within 30 days of receipt of this letter. Should you have any questions, you may contact us at (301) 827-6642.

Sincerely,

Mohammad T. Sharar, DVM, MSc
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine